Application No. 09/996,438
Filing Date: November 20,2001
Docket No. 5724-03-BHJ

IN THE CLAIMS

1. (currently amended) A pharmaceutical composition comprising:
an acid salt of a sympathomimetic amine; at least one additional active pharmaceutical ingredient; and at least one combination inhibitor, said combination inhibitor is selected from the group consisting of an amino polymer, a salt of a transition metal and combinations thereof, wherein each said combination inhibitor is a single component and is present in amounts sufficient to interfere with the isolation of said sympathomimetic amine and to interfere with the conversion of said sympathomimetic amine to other pharmacologically active compounds without significantly altering the release of said sympathomimetic amine from said pharmaceutical composition as compared to the undenatured composition.

Claims 2 – 31 (previously cancelled, without prejudice)

32. (previously presented) The pharmaceutical composition according to claim 1 further comprising at least one reaction inhibitor, wherein said reaction inhibitor is present in amounts sufficient to interfere with the conversion of said sympathomimetic amine to other pharmacologically active compounds without significantly altering the release of said sympathomimetic amine from said pharmaceutical composition as compared to the undenatured composition.

33. (previously presented) The pharmaceutical composition according to claim 1 further comprising at least one separation inhibitor, wherein said separation inhibitor is present in amounts sufficient to interfere with the isolation of said sympathomimetic amine without significantly altering the release of said sympathomimetic amine from said pharmaceutical composition as compared to the undenatured composition.

34. (previously cancelled, without prejudice)

35. (previously presented) The pharmaceutical composition according to claim 1 wherein said sympathomimetic amine is selected from the group consisting of pseudoephedrine hydrochloride, pseudoephedrine sulfate, ephedrine hydrochloride and phenylpropanolamine hydrochloride.

36. (previously presented) The pharmaceutical composition according to claim 35 wherein said sympathomimetic amine is pseudoephedrine hydrochloride.

37. (previously presented) The pharmaceutical composition according to claim 1 wherein said other pharmacologically active compound is selected from the group consisting of methamphetamine, amphetamine, methacathinone and cathinone.

38. (previously cancelled, without prejudice)

39. (previously presented) The pharmaceutical composition according to claim 1 wherein said amino polymer is a copolymer of methyl methacrylate, butyl methacrylate and dimethylaminoethyl methacrylate.

40. (previously presented) The pharmaceutical composition according to claim 39 wherein said amino polymer is the neutralized hydrochloride salt form of the copolymer of methyl methacrylate, butyl methacrylate and dimethylaminoethyl methacrylate.

41. (currently amended) The composition according to claim 1 wherein said ~~further comprising a~~ transition metal is selected from the group consisting of iron, cobalt, copper, chromium, manganese, nickel, zinc and combinations thereof

42. (previously presented) The composition according to claim 41 wherein the anion of said transition metal salt is selected from the group consisting of chloride, oxide, sulfate and gluconate.

43. (previously cancelled, without prejudice)

44. (previously presented) The pharmaceutical composition according to claim 42 wherein said transition metal salt is selected from the group consisting of ferrous gluconate, zinc gluconate, copper gluconate and combinations thereof.

45. (previously presented) The pharmaceutical composition according to claim 32 wherein said reaction inhibitor is selected from the group consisting of water insoluble polyhydroxy compounds, non-polymeric water soluble polyhydroxy compounds, solvent soluble ester compounds and combinations thereof.

46. (previously presented) The pharmaceutical composition according to claim 45 wherein said water insoluble polyhydroxy compound is selected from the group consisting of ethylcellulose, cellulose and combinations thereof.

47. (previously presented) The pharmaceutical composition according to claim 45 wherein said non-polymeric water soluble polyhydroxy compound is selected from

the group consisting of fructose, glycerin, sorbitol, lactitol, mannitol, xylitol, maltitol, galactose and combinations thereof.

48. (previously presented) The pharmaceutical composition according to claim 45 wherein said solvent soluble ester is selected from the group consisting of glycerin esters, esters of glycerin polymers, sorbitol esters, propylene glycol esters, polyethylene glycol esters, sucrose esters, esters of ethoxylated fatty alcohols and combinations thereof.

49. (previously presented) The pharmaceutical composition according to claim 33 wherein said separation inhibitor is selected from the group consisting of water soluble cellulose compounds, polysaccharide gums, polyethylene oxide polymers, acrylic acid polymers, starches, magnesium aluminum silicates, polyvinylpyrrolidones, clays and combinations thereof.

50. (previously presented) The pharmaceutical composition according to claim 1 wherein said amino polymer is from about 1% to about 100% in the neutralized salt form.

51. – 53 cancelled, without prejudice.

54. (new) The composition of claim 1, wherein said at least one additional active pharmaceutical ingredient is selected from the group consisting of antitussives, antihistamines, antiasthmatics, analgesics, non-steroidal anti-inflammatory drugs, expectorants and combinations thereof.

55. (new) The composition of claim 1, wherein said at least one additional active pharmaceutical ingredient is selected from the group consisting of dextromethorphan, dextromethorphan hydrobromide, noscapine, carbetapentane citrate, chlophedianol hydrochloride, chlorpheniramine maleate, phenindamine tartrate, pyrilamine maleate,

brompheniramine maleate, dexchlorpheniramine maleate, dexbromphenitamine maleate, doxylamione succinate, phenyltoloxamine citrate, diphenhydramine hydrochloride, promethazine and triprolidine hydrochloride; salbutamol [albuterol], terbutaline, carbuterol, broxaterol, aminophylline and theophylline, acetaminophen; acetylsalicylic acid, indomethacin, acemethacin, sulindac, piroxicam, ibuprofen, naproxen, ketoprofen; glyceryl guaiacolate, carbocysteine and combinations thereof.

56. (new) The composition of claim 1, wherein said at least one additional active pharmaceutical ingredient is selected from the group consisting of dextromethorphan, dextromethorphan hydrobromide, chlorpheniramine maleate, diphenhydramine hydrochloride, triprolidine hydrochloride, acetaminophen, ibuprofen, naproxen, ketoprofen, glyceryl guaiacolate, carbocysteine and combinations thereof.